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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,314	09/05/2006	Annie Bardat	1217-0171PUS1	1865

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
12/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/552,314	BARDAT ET AL.	
	Examiner	Art Unit	
	YUNSOO KIM	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *12-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-11* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/7/05, 2/13/06,11/28/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-14 are pending.

2. Applicant's election without traverse of Group I in the reply filed on 9/8/08 is acknowledged. Applicant traverses the restriction because the inventions I and II share a common technical feature and Applicant asserts that the claimed invention was novel in light of U.S Pat. 6,267,958 (corresponds to WO 97/04801) under PCT Rule 13.

However, the WO97/04801 was cited as a X reference in the search report mailed on 10/12/04 from the ISA and the claimed invention cannot be considered novel or cannot be considered to involve in an inventive step when the X reference is taken alone. The inventions of Groups I and II were found to have no special technical feature that defined the contribution over the prior art as represented by WO 97/04801 or U.S. Pat. No. 6,267,958. Therefore, under PCT Rule 13.1 and 13.2, unity of invention does not exist.

Applicants further traversed that the International Examiner did not object to unity of invention and the Office should apply the same standard as the PCT practice. However, national practice is not the same as international practice. For example, there is no equivalent of 35 U.S.C. 102(e) for international practice. Thus, the standards for examination differ between the international and national stages. The restriction requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 12-14 are withdrawn from further consideration by the examiner 37 CFR 1.142 (b) as being drawn to a nonelected invention.

Claims 1-11 are under consideration.

3. Applicant's IDS filed on 10/7/05, 2/13/05 and 11/28/06 have been acknowledged. Given that the IDS filed on 11/28/06 is a duplicate of the IDS filed on 10/7/05, the IDS filed on 11/28/06 has been crossed out.

4. Applicant's claim for foreign priority under 35. U.S.C. 119(a)-(d) is acknowledged.

5. Claim 2 is objected to as being dependent upon a rejected independent claim, but would be allowable if rewritten in independent form including all of the limitations of the independent claim and any intervening claims. Given that claim 2 recites the formulation in a closed language "consisting of", the formulation of claim 2 is limited to a lyophilized (or solid) form consists of sugar alcohol, glycine and non-ionic detergent. Note that the claimed composition does not comprise antibody, buffer, water or any other solvent or excipient.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3, 4 and 6-11 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S.Pat. No. 6,267,958 as is evidenced by the MSDS for mannitol.

The '958 patent teaches an IgG formulation comprising mannitol, glycine and non-ionic detergents such as Tween 20 (Table 2, col. 20-22). The '958 patent further teaches that formulations may be lyophilized or may be in liquid form (Table 2).

The '958 patent further teaches compositions wherein the concentration of mannitol is 250mM (table 2) and compositions wherein the concentration of polysorbate, a non-ionic detergent, is 0.005% (table 9).

Given that the molecular weight of mannitol is 182.17 as is evidenced by the MSDS for mannitol, 250mM of mannitol is equivalent to 45.5g/l and therefore, claim 4 is included. Moreover, ppm unit recited in claim 6 is "parts per million" and the range "20ppm to 50ppm" is equivalent to 0.002% to 0.005%. Therefore, claim 6 is included in this rejection.

Claims 9-11 are included in this rejection because the referenced formulation and the claimed formulation are identical in that they comprise mannitol, glycine and non-ionic detergent both in liquid and lyophilized form. Therefore, the referenced formulation inherently includes polymers less than 0.3% after 6 m at room temperature, polymers less than 0.3% after 12m at room

temperature or includes dimers less than 7% after 24m at 4°C as recited in claims 9-11. Therefore, the reference teachings anticipate the claimed invention.

8. Claims 1, 3, 5-7, 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S.Pat. No. 5,945,098 (IDS reference) as is evidenced by the MSDS for glycine.

The '098 patent teaches an aqueous IgG formulation comprising mannitol, glycine and non-ionic detergents such as Tween 20 (claims 1-12, examples 1-15).

The '958 patent further teaches that the concentration of glycine is about 0.1-0.3M, preferably about 0.2M (example 1, col. 5, lines 13-18, claim 1) and that the concentration of polysorbate is 0.002-0.004% (example 1).

Given that the molecular weight of glycine is 75.07 as is evidenced by the MSDS for glycine, "about 0.1M-0.3M" is equivalent to 7g/l to 21g/l, and thus claim 5 is included. Moreover, ppm unit recited in claim 6 is "parts per million" and the range "20ppm to 50ppm" is equivalent to 0.002% to 0.005. Therefore, claim 6 is included in this rejection.

Claims 9 and 11 are included in this rejection because the referenced formulation and the claimed formulation are identical in that they comprise mannitol, glycine and non-ionic detergent both in liquid and lyophilized form. Therefore, the referenced formulation inherently includes polymers less than 0.3% after 6 m at room temperature, or includes dimers less than 7% after 24m at 4°C as recited in claims 9 and 11. Therefore, the reference teachings anticipate the claimed invention.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable U.S. Pat. No. 5,945,098 in view of U.S. Pat. No. 6,267,958.

The '098 patent and the '958 patent have been discussed, supra.

The disclosure of the ‘098 patent differs from the instant claimed invention in that it does not teach the lyophilized as is currently recited in claim 8 of the instant application.

The ‘958 patent teaches that the lyophilization is a commonly employed technique for preserving protein to remove water from the protein preparation. The '958 patent further teaches lyophilization improves stability of protein upon storage and delivery (col. 1, lines 41-60).

Claims 10-11 are included in this rejection because upon lyophilization of protein, the referenced formulation is expected to include polymers less than 0.3% after 12 m at room temperature, or includes dimers less than 7% after 24m at 4°C as recited in claims 10 and 11.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to employ lyophilization method as taught by the ‘958 patent to the antibody formulation as taught by the ‘098 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the lyophilization improves stability of protein upon storage and delivery by removing water from the protein preparation.

From the teachings of the references, it would have been obvious to one of ordinary skill in the art to combine teachings of the references and there would have been a reasonable expectation to success in producing the claimed invention. Therefore, the invention as a whole was a prima facie obvious to one of ordinary skill in the art at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

11. No claims are allowable.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F,9-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
Patent Examiner
Technology Center 1600
December 1, 2008

/Michael Szperka/
Primary Examiner, Art Unit 1644